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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/490,312	01/24/2000	Gerhard P. Weber	P04358US0 PHI 1247	6990	
27310	7590 07/29/2002				
PIONEER HI-BRED INTERNATIONAL INC.			EXAMINER		
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JOHNSTON, I	JOHNSTON, IA 50131		ART UNIT	PAPER NUMBER	
			1638	<u></u>	
			DATE MAILED: 07/29/2002	1	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No. Applicant(s)					
	Office Action C	09/490,312	WEBER, GERHARD P.				
	Office Action Summary	Examiner	Art Unit				
;	The MAILING DATE AND	Ashwin Mehta					
	The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
	A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any  Status						
	20) This is a sure and a soft med of RCE filed 05/20/02.						
İ	2b) I his action is non-final						
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
	Disposition of Claims						
	4)⊠ Claim(s) <u>1-32</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
	5) Claim(s) is/are allowed.						
	6)⊠ Claim(s) <u>1-32</u> is/are rejected.						
	7) Claim(s) is/are objected to.						
	8) Claim(s) are subject to restriction and/or election requirement.						
1	Application Papers						
	9) The specification is objected to by the Examiner.						
	10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in the						
	is	s: a) ☐ approved b) ☐ disapprove	d by the Examiner				
	in approved, corrected drawings are required in reply to this Office action						
	12)[_] The oath or declaration is objected to by the Examiner.						
	Priority under 35 U.S.C. §§ 119 and 120						
	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
	a) All b) Some * c) None of:						
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No.						
	3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
	14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
l	a) Little translation of the foreign language provisional application has be						
A standard of a claim for domestic priority under 35 U.S.C. 88 120 and/or 124							
2) 3)	□ Notice of References Cited (PTO-892)     □ Notice of Draftsperson's Patent Drawing Review (PTO-948)     □ Information Disclosure Statement(s) (PTO-1449) Paper No(s)	4) Interview Summary (PTo S) Notice of Informal Patents 6) Other:	O-413) Paper No(s) t Application (PTO-152)				
vs.P. ot∩	atent and Trademark Office						

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#### **DETAILED ACTION**

## Request for Continued Examination

1. The request filed on 20 May 2002 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/490,312 is acceptable and a RCE has been established. An action on the RCE follows.

#### Specification

2. Page 7 of the specification remains objected to for the inclusion of blank lines where ATCC accession numbers should be. Inclusion of the numbers will overcome the objection. Applicants traverse the objection in the paper received 20 May 2002.

Applicants reiterate that they will refrain from depositing the lines until an indication of allowable subject matter has been issued (response, page 2, 2<sup>nd</sup> full paragraph). Applicant's intent is acknowledged. As the claims are not in condition for allowance, the objection is maintained.

## Claim Objections

3. Claims 1, 5, and 7 remain objected to for the inclusion of a blank line where the ATCC accession number should be. Inclusion of the number will overcome the objection. Applicants traverse the objection in the paper received 20 May 2002.

Applicants reiterate that they will refrain from depositing the lines until an indication of allowable subject matter has been issued (response, page 2, 3<sup>rd</sup> full paragraph). Applicant's intent is acknowledged.

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#### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-7, 9-14, 15-20, and 22-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,018,113. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed hybrid maize seed designated 39M27 of the present invention does not appear to be patentably distinct from the claimed hybrid maize seed designated 38W36 of 6,018,113. Plants derived from both seeds share numerous characteristics, and those which are not shared would be due to minor morphological variation, which would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 39M27. Further, the designation "39M27" does not distinguish the instantly claimed seeds and plants from 38W36, as this appears to be an arbitrarily assigned designation. The instantly claimed maize plants that have as at least one ancestor 39M27, or 39M27 containing one or more transgenes, would then

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be encompassed by the patented maize plants that have as at least one ancestor 38W36, or 38W36 containing one or more transgenes. As 39M27 and 38W36 are not patentably distinct, the claimed methods that comprise their use are obviously the same as well. A patent issuing from the instant application would then effectively extend the patent term of the claims of '113.

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant traverses the rejection in the paper filed 20 May 2002. Applicant's arguments were fully considered but were not found persuasive.

The recitation "39M27" in claims 1, 5, 7, 11, 15, 19, 24, 28, and 32 render the claims and those dependent thereon indefinite. Since the name "39M27" is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics which are associated with that denomination. The name "39M27" does not clearly identify the claimed hybrid maize seed, and does not set forth the metes and bounds of the claimed invention. In addition, the name appears to be arbitrary and the specific characteristics associated therewith could be modified, as there is no claimed description of the maize plant that encompasses all of its traits. Amending claims 1, 5, and 7 to recite the ATCC deposit number in which hybrid maize seed 39M27 has been deposited would overcome the rejection.

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Applicants reiterate that they will refrain from depositing the lines until an indication of allowable subject matter has been issued (response, page 3, 1<sup>st</sup> full paragraph). Applicant's intent is acknowledged.

In claims 11, 15, 19, 24, 28, and 32: the terms "excellent," "above average," "early," and "particularly suited" are relative terms that have no definite meaning. The terms do not reasonably apprise one of the scope of the invention. It is also not clear what type of yield, grain yield, pollen yield, seed yield, etc; the recitation "excellent yield potential" is referring to. The recitation "Northwest, Northcentral, Northeast regions of the United States" also renders the claims indefinite. It is not exactly clear what states or geographic areas define these regions.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 11-19 and 24-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any maize plant or its parts wherein at least one ancestor is 39M27 and expresses a combination of at least two 39M27 traits; or a hybrid maize plant grown from seed of 39M27, or which has all the morphological and physiological traits as

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the plant grown from 39M27 seed, and which contains one or more transgenes; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more transgenes; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more transgenes and which expresses at least two 39M27 traits; or a hybrid maize plant grown from 39M27 seed wherein the genetic material contains one or more genes transferred by backcrossing; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing and which expresses at least two 39M27 traits.

The specification describes morphological and physiological traits of a hybrid maize plant grown from hybrid maize seed arbitrarily designated "39M27", which was produced by crossing two inbred lines designated "GE516214" and "GE533139" (page 7, last paragraph; page 15; Table 1, pages 16-18). The specification also describes comparisons of 39M27 to other hybrid plants (page 19, Table 2 on pages 19-20, page 21, Table 3 on page 22, page 23, first paragraph and Table 4). The specification further indicates that upon allowance of any claims, all restrictions on the availability to a deposit of 2500 seeds of 39M27 with the American Type Culture Collection will be removed, that the deposit will be maintained without restriction, that all requirements of 37 CFR 1.801-1.809 will be met, and that the deposit will follow the requirements of 37 CFR 1.801-1.809 (page 37).

However, the specification does not describe the plants developed by the maize breeding programs, transgenic 39M27 plants, 39M27 plants further comprising genes transferred by

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backcrossing, or maize plants wherein at least one ancestor is corn variety 39M27 and which express at least two of the traits listed in claims 11, 15, 19, 24, 28, or 32. The morphological and physiological traits of the corn plants that are crossed with 39M27, and with progeny of that cross, are unknown, and the description of progeny and descendents of corn plant 39M27 are unknown. The description of corn plant 39M27 is not indicative of any of its descendents. To say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by 39M27. Two plant traits do not provide any description of the other traits of a plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant 39M27. For example, Weber (U. S. Patent No. 6,018,113) describes a corn plant designated "38W36," which expresses at least two traits that are also expressed by 39M27, good early growth and good roots, for example (col. 11, lines 3-4). The instantly claimed corn plants could have 38W36 as an ancestor, as well as 39M27, in which case the early growth and good root traits, for example, could have been inherited from 38W36. Further, it is not known what genes of 39M27 would be affected in the claimed methods comprising breeding programs. The traits of the plants produced by the programs are unknown, and not described by the specification. The transgenes, and genes introduced into 39M27 by backcrossing, may be of gene(s) that effect any trait or more than one trait. Such plants would express different morphological and physiological traits from 39M27, and which are not described. Given the breadth of the claims encompassing corn plants expressing at least two traits that are also expressed by 39M27, any transgenic 39M27 plant, any 39M27 plant further having any gene(s) introduced by backcrossing, methods comprising the use of such plants, lack of guidance of the

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specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

7. Claims 1-32 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants traverse the rejection in the paper received 20 May 2002. Applicant's arguments were fully considered but were not found persuasive.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that applicants intend to deposit seeds for 39M27 at the ATCC, but there is no indication that the seeds have been deposited. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must by maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

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- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
  - (e) the deposit will be replaced if it should ever become inviable.

Applicants reiterate that they will refrain from depositing the lines until an indication of allowable subject matter has been issued (response, page 4, 1<sup>st</sup> full paragraph). Applicant's intent is acknowledged. As the claims are not in condition for allowance, the rejection is maintained.

# Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 1-32 are rejected under 35 U.S.C. § 102 (e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over Weber (U.S. Patent No. 6,018,113). Applicant traverses the rejection in the paper received 20 May 2002. Applicant's arguments were fully considered but were not found persuasive.

The claims broadly encompass a plant, or parts thereof, having characteristics of hybrid maize plant 39M27, a seed or progeny derived from maize plant 39M27, maize plants derived from 39M27, tissue culture derived from 39M27, methods of using said plant in a breeding program.

Weber teaches hybrid maize plant and seed 38W36. It appears that the claimed plants and seeds of the instant invention may be the same as 38W36, given that each has exceptional grain yield potential, excellent resistance to European corn borer, and particularly suited to the Northwest, North Central, and Northeast regions of the United States as well as to Canada (col. 10, line 65 col. 11, line 6), for example. Alternatively, if the claimed plants, plant parts, and seeds of 39M27 are not identical to 38W36, then it appears that 38W36 only differs from the claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to

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39M27. Weber also teaches a plant produced from tissue culture of 38W36 or a hybrid plant of 38W36, and maize plant pedigree breeding comprising techniques which include backcrossing, recurrent selection, etc. (col. 3, line 50 to col. 5, line 9; col. 15, line 64 to col. 17, line 14). Introduction of other genes into 38W36 via genetic engineering or breeding, and transfer of transgenes from a transgenic plant to a non-transgenic plant through crosses is also taught (col. 17, line 15 to col. 25, line 54). Weber also teaches how to confer male sterility trait to 38W36, and that it would be desirable to do so, for example, to avoid the laborious and unreliable detasseling process used during production of hybrid maize seed (col. 1, line 63 to col. 2, line 50). As cultivar 38W36 is the same as cultivar 39M27, the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Weber.

Applicant argues that the claims recite specific traits only to the extent that they are "39M27" traits, thereby coming solely from 39M27 seed/germplasm. Applicants argue that the claims also recite that the claimed plant must have 39M27 as an ancestor. Applicants argue that one can tell from breeding history if the claimed plant has 39M27 as an ancestor, and that its unique genetic background will result in the claimed plant (response, paragraph bridging pages 4-5). However, the claimed plants can also have as parents other corn plants that also express the listed traits, and inherit unique genetic profile governing the traits from that parent. The specification does not teach how or why the genetic profile of 39M27, which governs the traits enumerated in the claims, differs from that of other plants, such as 38W36, that also express two or more of these traits.

Applicant also argues that it is not the phenotypic characteristics alone that are claimed, but the combination of physiological and morphological characteristics, and that there are several differences between 38W36 and 39M27, as evidenced by Tables 2-4 (response, paragraph

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bridging pages 5-6). However, the claims only require a combination of two of the listed traits, not all of them.

9. No claims are allowed.

## **Contact Information**

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdasy and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ASHWIN D. MEHTA, PH.D. PATENT EXAMINER

July 22, 2002